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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------|
| 09/467,928 | 12/21/1999 | DAVID GAILLAC | 017753-120 | 2965 |
| 21839 | 7590 | 06/15/2005 | EXAMINER | |
| BURNS DOANE SWECKER & MATHIS L L P POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404 | | | | PARKIN, JEFFREY S |
| ART UNIT | | PAPER NUMBER | | |
| | | | | 1648 |

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/467,928 | GAILLAC ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey S. Parkin, Ph.D. | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 March 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5-7,10-12 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 5-7, 10-12, and 18-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Serial No.: 09/467,928

Applicants: Gaillac, D., and M. Koehl

Docket No.: 017753-120

Filing Date: 12/21/99

Detailed Office Action

Status of the Claims

Claims 1, 5-7, 10-12, and 18-28 are pending in the instant application.

35 U.S.C. § 112, Second Paragraph

Claims 1, 5-7, 10-12, and 18-28 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Claims 1, 5-7, 10-12, and 18-28 remain vague and indefinite for omitting essential positive methods steps, such omission amounting to a gap between the steps (refer to M.P.E.P. ¶ 2173.05(q)). *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (Bd. Pat. App. & Inter. 1986). The claims have been amended to provide additional limitations pertaining to the solvent, temperature, and pH. However, the claims still omit several important steps (i.e., the recovery of virus from a producer cell line; the treatment of virus with Benzonase and TWEEN 80 to remove cellular debris; and recovery of the virus by some type of filtration process (i.e., ion-exchange chromatography)). Appropriate correction is still required.

Applicants argue that the claim amendments obviates the rejection. This argument is not deemed to be persuasive. The method as currently claimed is still incomplete. The method is directed toward a method of inactivating contaminating enveloped

viruses in an adenoviral preparation. Reagents are added to the preparation to inactivate said contaminants, but the claims fail to set forth any additional recovery or purification steps. In order for the skilled artisan to use the preparation additional steps are required that relate to the preamble. Applicants' representative is invited to contact the examiner to discuss potential revisions to the claim language that might obviate the existing rejection.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-7, 10-12, and 18-28 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are broadly directed toward a method of inactivating enveloped viruses contaminating adenoviral preparations by treating said preparations with any given solvent at a wide range of pHs and temperatures. The disclosure provides an inactivation protocol involving recombinant adenoviral preparations and specific inactivation steps involving treatment with 0.3% tri-n-butyl phosphate (TNBP), 1% TWEEN 80, and benzonase. Appropriately drafted claim language directed toward this embodiment would be acceptable (i.e., A method of inactivating enveloped viruses in a preparation containing recombinant adenoviruses comprising the following steps: 1) releasing intracellular adenovirus from an infected cell line;

2) treating the released viral preparation with benzonase and TWEEN 80; 3) filtering the preparation to remove cellular debris; 4) inactivating the viral preparation through the administration of 0.6% TNBP at a pH of 8.5; 5) passing the inactivated preparation over an ion-exchange column and isolating the inactivated recombinant adenoviral preparation). The disclosure is not enabled for the full breadth of the claim language which encompasses any manner of making inactivated viral preparations.

As previously set forth, the legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

- 1) The disclosure fails to provide a sufficient number of method steps to perform and complete the claimed methodology. As noted *supra* in the 35 U.S.C. § 112, second paragraph, rejection, the claims omit a number of salient steps that are required for completion.
- 2) The disclosure fails to provide a reasonable number of working embodiments. All of the examples employed TNBP (0.3% final concentration), 2% TWEEN 80, pH 8.5, and a temperature of 4°C. The

disclosure fails to describe the utilization of any other solvents, detergents, or reaction conditions. Accordingly, when all the aforementioned factors are considered *in toto*, the skilled artisan would reasonably conclude that undue experimentation would be required to practice the claimed invention.

Applicants argue that the specification is fully enabling. These arguments are not persuasive. As set forth above, the claims omit a number of critical methodology steps that are required to inactivate the contaminating enveloped viral preparations.

Trademarks (M.P.E.P. § 608.01(v))

The use of the trademark "Tween" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Each letter of the word should be capitalized (e.g., TWEEN) or a proper trademark symbol, such as TM or [®], should follow the word (e.g., Tween[®]).

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R.

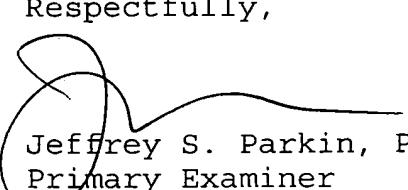
S 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

10 June, 2005